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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/553,941	03/20/2007	Patrick Leahy	KEL01 P-145	6131

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EXAMINER

COTRONEO, STEVEN J

ART UNIT	PAPER NUMBER
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3733

MAIL DATE	DELIVERY MODE
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01/27/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/553,941	Applicant(s) LEAHY, PATRICK	
	Examiner STEVEN J. COTRONEO	Art Unit 3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 October 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/20/2005</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2-4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claims 2 and 3 recites the broad recitation "adjacent the exit aperture," and the claim also recites "*preferably* at the exit aperture," which is the narrower statement of the range/limitation.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

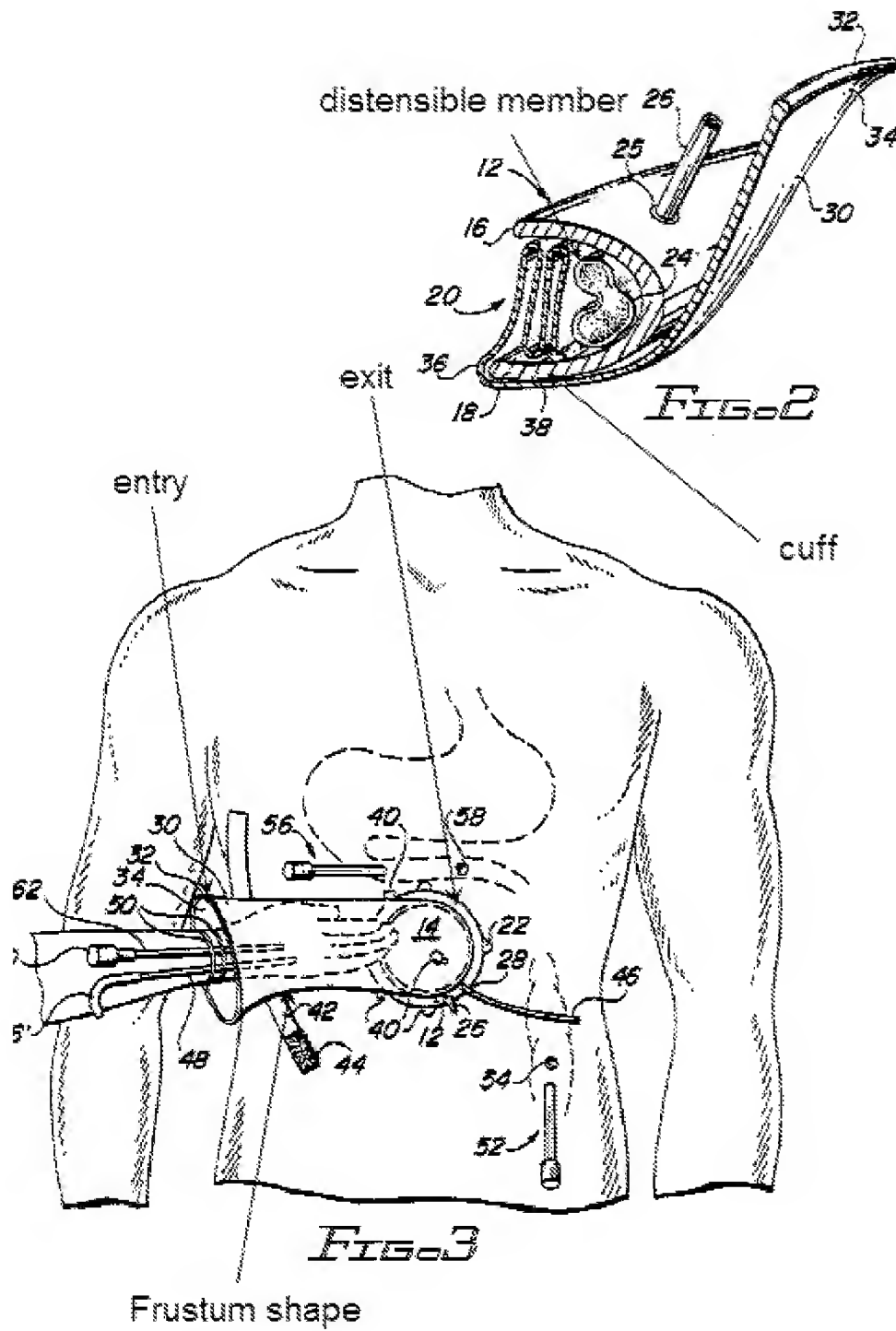
A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 5-13, 15 and 19-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Leyva (US 5,522,791).

Leyva discloses a surgical device (see figures 2 and 3 below) for use in minimally invasive surgery, the device comprising a sleeve (fig 3, 30) having an exit aperture (fig 3, 14) and an entry aperture (fig 3, 34), the sleeve being shaped and dimensioned to permit the passage of a hand therethrough (fig 3); and a distensible member (fig 2) secured to or formed integrally about the sleeve adjacent the exit aperture. The distensible member annularly located circumferentially at the exit aperture on the exterior of the sleeve (fig 2). The sleeve has a frustum shape with the larger cross section at the entry aperture (fig 3, top is wider). The sleeve is flexible and fluid impermeable (col. 4, ll. 13-16, "latex rubber, plastic or vinyl"). The entry aperture has a reinforcing member (fig 3, 32 and col. 4, ll. 15-20, "gripping loop... resilient flexible material"). A sealing means including a one way valve (fig 3, 40) is provided. A cuff is located around the exit aperture (fig 2, 18).

Leyva discloses the method of passing a hand through the sleeve (fig 3), inserting the distensible member into the surgically cavity and distending the member (col. 6, ll. 1-17).



Claims 1-13 and 15-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Beane et al. (US 6,142,936).

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Leyva discloses a surgical device (see figure 1 below) for use in minimally invasive surgery, the device comprising a sleeve (fig 1) having an exit aperture (fig 1, 18) and an entry aperture (fig 1, 12), the sleeve being shaped and dimensioned to permit the passage of a hand therethrough (fig 11); and a distensible member (fig 1, 68 and 69) secured to or formed integrally about the sleeve adjacent the exit aperture. The distensible member annularly located circumferentially at the exit aperture on the exterior of the sleeve in a plurality of sections (fig 1). The sleeve has a frustum shape with the larger cross section at the entry aperture (fig 1, 10 is wider than 66). The sleeve is flexible and fluid impermeable (col. 13, ll. 18-22, "rubber, plastic"). The sleeve can be transparent (col. 13, ll. 6, "the skirt pocket transparent"). The entry aperture has a reinforcing member (fig 1, 10). A sealing means including a one way valve (fig 1, 14) is provided. A cuff is located around the exit aperture (fig 1, 63). The sleeve has a passage along its length (fig 13, 142). A cover is releasably secured to the entry aperture (fig 7B).

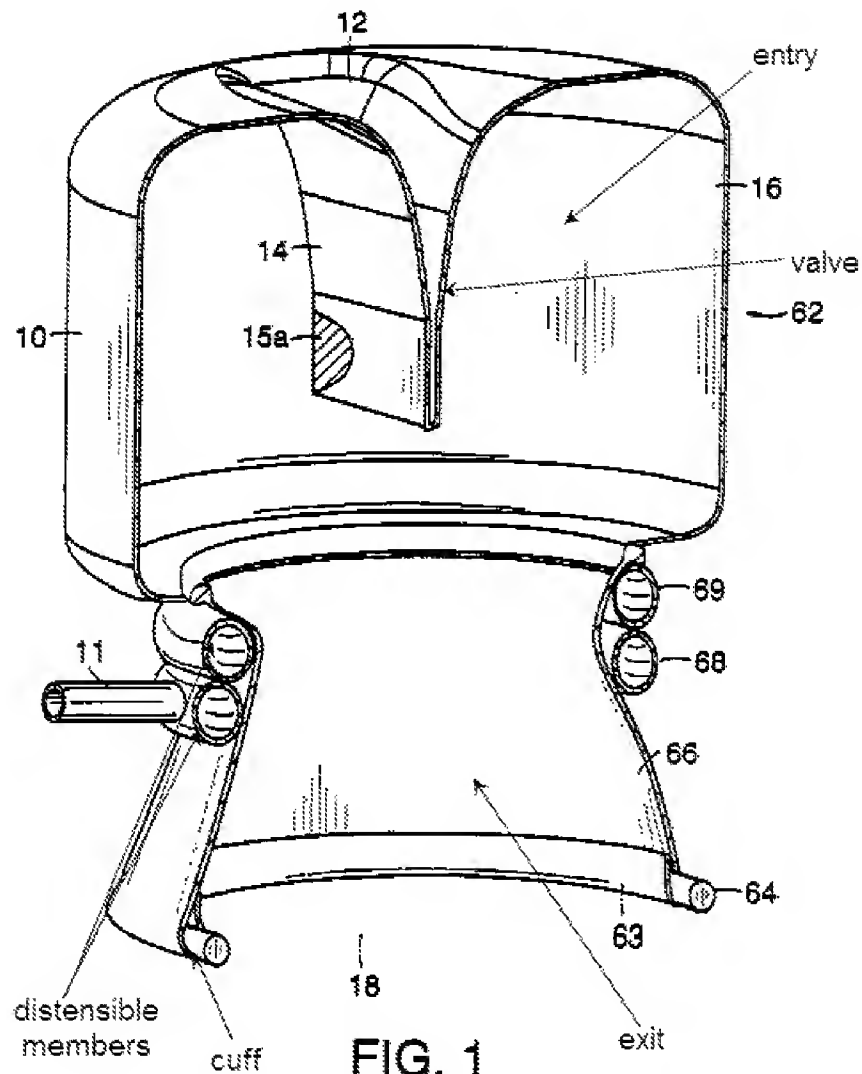


FIG. 1

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Leyva (US 5,522,791) in view of Leahy et al. (US 5,640,977).

Leyva discloses the claimed invention except for the sleeve being provided with lubricant.

Leahy et al. discloses a surgical sleeve provided with lubricant (col. 4, ll. 46) to reduce the friction and ease movement of the hand (col. 4, ll. 45-47).

It would have been obvious at the time of the invention to one of ordinary skill in the art to modify the device of Leyva to include the sleeve being provided with lubricant in view of Leahy et al. in order to reduce the friction and ease movement of the hand.

Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Beane et al. (US 6,142,936) in view of Leahy et al. (US 5,640,977).

Beane et al. discloses the claimed invention except for the sleeve being provided with lubricant.

Leahy et al. discloses a surgical sleeve provided with lubricant (col. 4, ll. 46) to reduce the friction and ease movement of the hand (col. 4, ll. 45-47).

It would have been obvious at the time of the invention to one of ordinary skill in the art to modify the device of Beane et al. to include the sleeve being provided with lubricant in view of Leahy et al. in order to reduce the friction and ease movement of the hand.

Conclusion

The prior art made of record on PTO-892 and not relied upon is considered pertinent to applicant's disclosure.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to STEVEN J. COTRONEO whose telephone number is (571)270-7388. The examiner can normally be reached on M-F 730-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. J. C./
Examiner, Art Unit 3733

/Eduardo C. Robert/
Supervisory Patent Examiner, Art Unit 3733